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(via Federal Express)

1752 '99 MAY 11 AD 37



Dockets Management Branch, HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: **Docket No. 99D-0254**  
Product Name Placement, Size, and Prominence  
in Advertising and Promotional Labeling

Dear Sir or Madam:

As a leader in the U.S. pharmaceutical industry, Merck & Co., Inc., supports DDMAC's recent efforts to issue updated guidance documents that reflect the Agency's current thinking on a variety of promotional issues. With its many years of experience in the discovery, development, production, and marketing of human health and biological products, Merck recognizes the impact that time and events can have on agency guidance documents. Maintaining the currency of core guidance documentation requires careful, continuous attention from the Agency and provides both DDMAC and industry with the opportunity to re-visit and clarify issues, as needed, to maintain their relevance over time.

Merck appreciates the opportunity to respond to the March 12, 1999, Federal Register notice requesting industry comments on draft guidance identified as Docket No. 99D-0254, concerning the placement, size, and prominence of product names in advertising and promotional labeling. Merck's comments are as follows:

## II. PRODUCTS WITH ONE ACTIVE INGREDIENT

### A. JUXTAPOSITION OF PROPRIETARY NAME AND ESTABLISHED NAME.

#### "Direct conjunction" and "No intervening matter"

FDA interprets the regulations concerning product name placement as "...precluding separation of the proprietary or trade name and the established or proper name by placement of a logo, trademark, or other graphic matter, or otherwise physically separating the proprietary and established name." The description of product name placement continues in the draft guidance with the statement: "[t]here should be no intervening matter that in any way would detract, obfuscate, or de-emphasize the established or proper name of the product."

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To ensure trademark protection, it is customary for labeling and promotional materials to include (in featured copy and in running text) a typographic symbol to designate the product's appropriate trademark status – either:

- 1) registered trademark, indicated with the symbol “®”; or
- 2) trademark, indicated with the symbol “™”.

In the past, FDA has not objected to the inclusion of a trademark symbol following the product's proprietary name. Merck suggests clarification from FDA that these typographic devices would not be considered violative under the draft guidance as they do not “detract, obfuscate, or de-emphasize the established or proper name of the product.”

In addition, current industry practice includes the use of product logo clusters that contain minor “fanciful” graphic devices that call attention to both the proprietary and established names of a product without detracting from an accurate reading of either name. Merck suggests FDA clarification that such minor graphic devices that do not “detract, obfuscate, or de-emphasize the established or proper name of the product” would still be permissible under the draft guidance.

In the event FDA determines that a product logo cluster in use (without prior objection from FDA) at the time of publication of the draft guidance is no longer acceptable under the draft guidance, Merck suggests that adequate time (e.g., one year) be allowed for sponsors to deplete current inventories of materials affected by this re-interpretation of FDA's regulations.

#### C. PROMINENCE OF PROPRIETARY AND ESTABLISHED NAMES

Merck would like to request that FDA provide more specific guidance on its interpretation of the requirement that: “the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears....” In recognition that the appropriate application of the term “prominence commensurate” involves an important but somewhat subjective determination, Merck respectfully recommends that additional guidance be provided to illustrate acceptable and unacceptable examples.

#### D. PROPRIETARY AND ESTABLISHED NAMES IN AUDIO-VISUAL AND BROADCAST ADVERTISEMENTS AND PROMOTIONAL LABELING

The last sentence of this section in the draft guidance should be clarified to read as follows: “The established name should also have the same

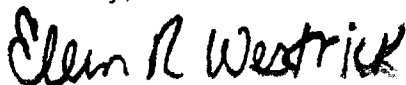
exposure time as that given to the proprietary name when it is most prominently displayed." Without this clarification, the sentence could be interpreted to mean that the established name must run simultaneously with each display of the proprietary name.

E. PROPRIETARY AND ESTABLISHED NAMES IN THE RUNNING TEXT OF  
ELECTRONIC AND COMPUTER-BASED ADVERTISEMENTS AND PROMOTIONAL  
LABELING

The draft guidance acknowledges that the regulations stating "...the established name shall be used at least once in the running text [not featured text] in association with such proprietary name or designation..." may be difficult to apply in the context of text pages for electronic and computer-based media which may extend beyond the length of a traditional print page. Of the four suggestions provided for fulfilling this requirement, Merck would consider any but the first option ("...established name accompanies the proprietary name each time..." ) to be reasonable means to comply with the once-per-running-text page obligation. Merck considers the first option to be overly restrictive and beyond the intent of the regulations which require "...proper identification of such products to help ensure their safe and effective use."

As stated above, Merck welcomes the opportunity to provide comments to FDA on draft guidance materials. If the Agency has any particular questions about this response or would like additional information, please contact my office. I would be happy to discuss this matter further at that time.

Sincerely,



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